K132274
Page 1 of 4

510(k) Summary of Safety and Effectiveness
Aixplorer® Diagnostic Ultrasound System

This summary of safety and effectiveness information is submitted in accordance with 21 CFR §807.92.

1) Submitter's name, address, telephone number, contact person

Submitted by:
SuperSonic Imagine, S.A.
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510, rue René Descartes
13857 Aix-en-Provence Cedex
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SEP 2 4 2013

Aurelie Gruener, Sr. Manager, Regulatory Affairs

Tel: 011 33 442 99 24 39
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2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name: Diagnostic Ultrasound System with Accessories
Proprietary Name: Aixplorer®

Classification: Regulatory Class: II

Classification Name:	**21 CFR Section**	**Product Code**
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Substantially Equivalent/Predicate Device
AIXPLORER® Ultrasound Imaging Systems (K112255 cleared on 08/28/2013 and K121329 cleared on 08/24/2013).

4) Description of Device

The SuperSonic Imagine AIXPLORER® system is a cart based ultrasound imaging system used to perform invasive and non-invasive diagnostic general purpose ultrasound imaging studies. The system contains a scan converter and can be coupled to a variety of linear, curved, micro-convex, and motorized linear array transducers to produce images, which are displayed on a LCD monitor. An adjustable control panel with integrated touch screen allows the user to perform an ultrasound exam quickly and efficiently in accordance with ALARA principles. The system also allows the user to perform measurements, capture images to digital memory or to an external device (such as a printer), and review diagnostic studies in the form of a report. The system functions in a manner identical to the predicate devices and transducers for the imaging modes: B-Mode, Color Flow, Pulsed Wave Doppler, Harmonic Imaging, Amplitude Doppler, 3D imaging, Panoramic Imaging and for ShearWave™ elastography. The addition of the quantification tool allows the user to read the average shear wave propagation speed.

5) Intended Use

The SuperSonic Imagine AIXPLORER® ultrasound system and transducer are intended for general purpose pulse echo ultrasound imaging, Doppler fluid flow analysis of the human body, and tissue elasticity imaging of soft tissues.

6) Safety Considerations

As a Track 3 ultrasound device, the SuperSonic Imagine AIXPLORER® ultrasound system is designed to comply with the NEMA UD 3 (2004), Standard For Real Time Display Of Thermal And Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment, and NEMA UD 2 (2004), Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.

With respect to limits on acoustic outputs, the SuperSonic Imagine AIXPLORER® ultrasound system complies with the FDA guideline limits set in the September 9, 2008, 510(k) diagnostic ultrasound guidance.

With regard to general safety, the SuperSonic Imagine AIXPLORER® ultrasound system is designed to comply with IEC 60101 -1 (2005) Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance, IEC 60601 - 2-37 (2007): Particular Requirements For The Safety Of Ultrasonic Medical Diagnostic And Monitoring Equipment and IEC 60601-1-2 (2000) Medical Electrical Equipment – part 1-2, General Requirements for Safety – Collateral Standard Electromagnetic Compatibility.

The device's acoustic output limits are:

Mechanical Index	1.9 (Maximum)
TIS/TIB	0.1 – 4.0 (Range)
ISPTA (d)	720 mW/cm2
ISPPA (d)	0 – 700 W/cm2

The limits are the same as predicate Track 3 devices. These considerations apply to all modes the system offers.

7) Comparison to Predicate Devices

The SuperSonic Imagine AIXPLORER® system is substantially equivalent to the predicate device with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are both intended for diagnostic ultrasound imaging and fluid flow analysis.
- The systems have the same clinical intended use.
- The systems have the same B-Mode (grayscale imaging) and Doppler capabilities.
- The systems' have the same adjustable numeric scale next to the color bar, for ShearWave™ Elastography.
- The systems have similar capability in terms of harmonic imaging, spatial compound imaging, elastography imaging and other image post-processing features to improve the image quality and aid in clinical evaluation and diagnosis.
- The transducers are similar in materials, manufacture and clinical capability.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The systems have been found to be manufactured in compliance with approved electrical and physical safety standards.
- In addition to the adjustable SWE numeric scale, the new device has the functionality that enables the user to place a region of interest (ROI) (also referred to as QBox) within the image and read the average shear wave propagation speed, plus the minimum, maximum and variance of the distribution of shear wave propagation speed values within the ROI. With this functionality, the user could appreciate quantitatively differences in shear wave propagation speeds between different structures. With the new device, the labeling for the adjustable SWE numeric scale as well as the SWE ROI quantification values shall be in kPa or m/s.

8) Non Clinical Performance Data/Bench Tests

The following non clinincal testing was performed on the modified Aixplorer to ensure continued safety and effectiveness:

- Shear wave speed Bias and Precision Tests –

  SWE estimation bias and precision measurements were made using four different cylindrical target types of a CIRS 049A Elasticity Quality Assurance phantom (nominal shear wave speeds between 1.6 and 5.2 m/s). These measurements were made for all of the transducers listed in the K112255 510(k).

  Estimation bias was derived as the difference between the mean of five independent SWE shear wave speed measurements and the nominal shear wave speed, normalized by the nominal shear wave speed and expressed as a percentage.

SWE estimation precision was derived as the standard deviation of five independent SWE shear wave speed measurements normalized by the mean of the five independent SWE measurements, and expressed as a percentage.

- QBox Measurement Tests –
  These tests demonstrated that the comparison between the SWE QBox/ROI measurements performed by the Aixplorer vs the results obtained by performing the same measurements in Matlab were within 5%.

9) Conclusion

The SuperSonic Imagine AIXPLORER® system is substantially equivalent to the predicate devices in safety and effectiveness. This is demonstrated by:

- There are no new questions of safety and effectiveness concerning the SuperSonic Imagine AIXPLORER® ultrasound system and transducers.
- The system and predicate devices are intended for general purpose pulse echo ultrasound imaging, Doppler fluid flow analysis of the human body, and tissue elasticity imaging of soft tissues.
- The system and predicate devices have been designed, manufactured and tested to the same electrical and physical safety standards.
- The system's and predicate devices' acoustic power levels are below the applicable FDA limits.
- The effectiveness of the new device was demonstrated in the non clinical testing conducted by SSI.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 24, 2013

SuperSonic Imagine, S.A.
% Mr. Jacques Souquet
Les Jardins de la Duranne
510 Rue René Descartes – Bât. E et F
Aix -en-Provence Cedex 13 857
FRANCE

Re: K132274
Trade/Device Name: Aixplorer®
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: August 27, 2013
Received: September 6, 2013

Dear Mr. Souquet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Aixplorer®, as described in your premarket notification:

Transducer Model Numbers

SL15-4	SE12-3	SL10-2
SC6-1	SLV16-5	SMC12-3

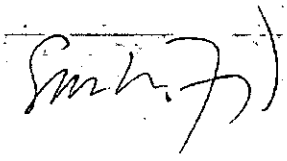
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Diagnostic Ultrasound Indications for Use

510(k) number: K132274
Device Name: AIXPLORER® Ultrasound System

Indications for Use:
The SuperSonic Imagine AIXPLORER® ultrasound system is indicated for use in the following applications: Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal and Neonatal Cephalic.

The system also provides the ability to measure anatomical structures (Abdominal, Small Organs, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular, GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal, Neonatal Cephalic).

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) _____K132274_____

Diagnostic Ultrasound Indications for Use

510(k) number: K132274
Device Name: AIXPLORER® Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal (including urolology)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 10
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 10
	Small Organ (Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 10
	Neonatal Cephalic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 9
	Adult Cephalic							
	Trans-rectal	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8
	Trans-vaginal	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 10
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 10
	Intravascular							
	GYN	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 10
	Pelvic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 10
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9, 10
	Other (Specify)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:

1: Combined modes include: B+ Color Flow	2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave	4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging	6: Spatial Compounding
7: ShearWave™ Elastography	8: Imaging Guidance for Biopsies
9: Panoramic Imaging	10: 3D Imaging

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number : K132274
Device Name: SL15-4 transducer (1D Linear Array Transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, Penis)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Neonatal Cephalic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Musculo-skeletal (Superficial)	P		P		P	P 1, 2, 3. 4	P 5, 6, 7, 8, 9
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 9
	Other (Specify)							

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:

1: Combined modes include: B+ Color Flow	2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave	4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging	6: Spatial Compounding
7: ShearWave™ Elastography	8: Imaging Guidance for Biopsies
9: Panoramic Imaging	10: 3D Imaging

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)
Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number : K132274
Device Name: SC6-1 transducer (curved array transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal (including urology)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Small Organ (Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Musculo-skeletal (Superficial)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Intravascular							
	GYN	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Pelvic	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Other (Specify)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:

1: Combined modes include: B+ Color Flow	2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave	4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging	6: Spatial Compounding
7: ShearWave™ Elastography	8: Imaging Guidance for Biopsies
9: Panoramic Imaging	10: 3D Imaging

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)
Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number : K132274
Device Name: SE12-3 transducer (endocavitary transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Trans-vaginal	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	GYN	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Pelvic	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:

1: Combined modes include: B+ Color Flow	2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave	4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging	6: Spatial Compounding
7: ShearWave™ Elastography	8: Imaging Guidance for Biopsies
9: Panoramic Imaging	10: 3D Imaging

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)
Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number : K132274
Device Name: SLV16-5 transducer (motorized linear transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 10
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 10
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 10
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 10
	Musculo-skeletal (Superficial)	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 10
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	P		P		P	P 1, 2, 3, 4	P 5, 6, 7, 8, 10
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:

1: Combined modes include: B+ Color Flow	2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave	4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging	6: Spatial Compounding
7: ShearWave™ Elastography	8: Imaging Guidance for Biopsies
9: Panoramic Imaging	10: 3D Imaging

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)
Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use

510(k) Number : K132274
Device Name: SL10-2 transducer (linear transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Neonatal Cephalic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Other (Specify)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:

1: Combined modes include: B+ Color Flow	2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave	4: Combined modes include: B+ Pulsed Wave + Color Flow
5: Harmonic Imaging	6: Spatial Compounding
7: ShearWave™ Elastography	8: Imaging Guidance for Biopsies
9: Panoramic Imaging	10: 3D Imaging

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Diagnostic Ultrasound Indications for Use

510(k) Number : K132274
Device Name: SMC12-3 transducer (micro-curved transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Small Organ (for example Breast, Thyroid, Testicle, Prostate, penis, etc...)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Neonatal Cephalic	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Musculo-skeletal (Superficial)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Intravascular							
	GYN							
	Pelvic							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9
	Other (Specify)	P		P		P	P, 1, 2, 3, 4	P, 5, 6, 7, 8, 9

N = new indication; P = previously cleared by FDA (K121329)

Additional Comments:

1: Combined modes include: B+ Color Flow	2: Combined modes include: B+ ShearWave™ Elastography
3: Combined modes include: B+ Pulsed Wave	4: Combined modes include: B+ Pulsed Wave + Color Flow
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7: ShearWave™ Elastography	8: Imaging Guidance for Biopsies
9: Panoramic Imaging	10: 3D Imaging

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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